

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0324]

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International Conference on Harmonisation; Draft Guidance on M5 Data
Elements and Standards for Drug Dictionaries; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "M5 Data Elements and Standards for Drug Dictionaries." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes the data elements and standards that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance is intended to facilitate the exchange and practical use of medicinal product information at the international level, such as with postmarketing safety reporting.

DATES: Submit written or electronic comments on the draft guidance by [insert date ⁴⁵ ~~90~~ days after date of publication in the **Federal Register**]. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single

copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7784; or Ann Schwartz, Center for Biologics Evaluation and Research (HFM-475), Food and Drug Administration, 1401 Rockville Pike, rm. 300N, Rockville, MD 20832, 301-827-3070.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking

scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of ICH's sponsors and IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In May 2005, the ICH Steering Committee agreed that a draft guidance entitled "M5 Data Elements and Standards for Drug Dictionaries" should be made available for public comment. The draft guidance is the product of the M5 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the M5 expert working group.

The draft guidance describes the data elements that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance outlines each data element and provides recommended standards for the data elements. The draft guidance addresses medicinal products (drugs and biologics) and is intended to accomplish the following goals:

- Improve the exchange of medicinal product information,
- Improve consistency in evaluating and comparing medicinal products for postmarketing surveillance activities,
- Provide consistent terminology for the health care community, and
- Reduce administrative burdens for the pharmaceutical industry when complying with different regional regulatory requirements.

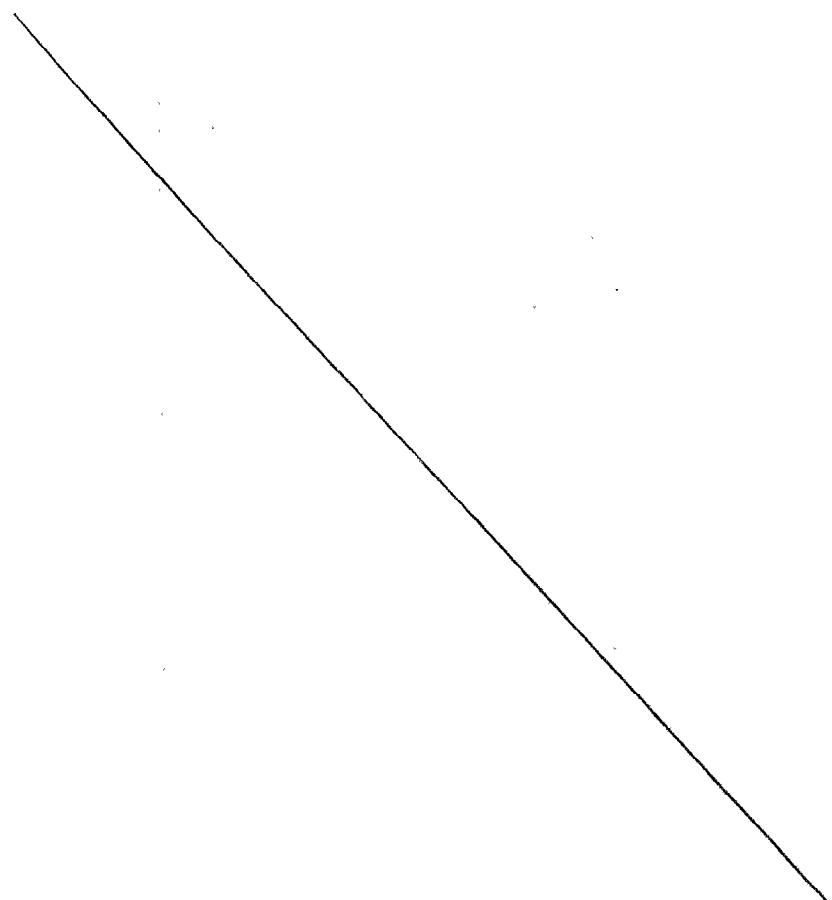
The draft guidance refers to approved medicinal products. The draft guidance does not apply to homeopathic medicinal products or investigational medicinal products. The draft guidance does not cover the establishment and maintenance of a drug dictionary.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on M5 data elements and standards for drug dictionaries. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed

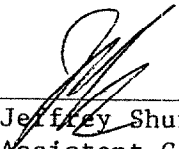
comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/reading.htm>.

Dated: 8/29/05
August 29, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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